UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 5, 1990

Mr. William M. Teringo
PDMP, Inc.
105 Loudoun Street SW
Leesburg, Virginia 22075

Dear Mr. Teringo:

Thank you for your letter of May 10, 1990, in which you requested information regarding the 40 CFR Part 259 requirements for medical waste packaging. Your letter indicates that your company manufactures a "nonmechanical incapacitation syringe safety needle guard." Your product appears to be a needle sheath containing a membrane with an adhesive which can be punctured during needle recapping.

As noted in your letter, Section 11003(a) of the Medical Waste Tracking Act (MWTA) does require "placement of the waste in containers that will protect waste handlers and the public from exposure." The MWTA also required EPA to draft regulations for medical waste management including packaging, labeling, and marking for regulated medical waste (RMW). The art 259 regulations are currently effective in five States (New York, New Jersey, Rhode Island, Connecticut and Puerto Rico). Wastes generated from the provision of home health care, however, are excluded by statute from the Part 259 regulations.

Consequently, RMW generated during the provision of medical services outside the home, in one of the Covered States, would be subject to the requirements of Part 259. Section 259.41(a) and (b) requires RMW which is shipped off-site to be packaged in container(s) which are rigid, leak-resistant, impervious to moisture, of sufficient strength to prevent tearing and bursting under normal conditions, and sealed. In addition, sharps are required to be packaged in puncture-resistant container(s) that are properly labeled and marked. The technical corrections to the Part 259 regulations (See 55 FR 27231, July 2, 1990) defines the term "container" as any portable device in which a RMW is stored, transported, disposed or otherwise handled. The term container as used in this part does not include items in the Table of Regulated Medical Waste in Section 259.30(a). Therefore, it does not appear that the safety needle sheath manufactured by PDMP can meet the Part 259 definition of container.

Proper containment and management procedures for materials before they become waste, including recapping of syringes, is subject to the requirements of the Occupational Safety and Health Administration (OSHA). You may want to contact the OSHA office near you for more information.

If you have any questions regarding this matter, please contact Mary Greene of my staff at (202) 475-8551.

Sincerely,

David Bussard, Director
Characterization and Assessment

FaxBack #11555